

climacteric and functional insufficiency." Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

**DISPOSITION:** June 8, 1948. The Basic Endocrines Sales Co., Inc., having been permitted to withdraw its claim in the matter, judgment of condemnation was entered and the products were ordered destroyed.

**2402. Misbranding of Electronic Device. U. S. v. 5 \* \* \*. (F. D. C. No. 24176. Sample No. 6216-K.)**

**LIBEL FILED:** January 14, 1948, Western District of Pennsylvania.

**ALLEGED SHIPMENT:** On or about November 13, 1947, by Saul Brothers, Inc., from Bronx, N. Y.

**PRODUCT:** 5 Electronic Devices at Pittsburgh, Pa.

**LABEL, IN PART:** "United Diathermy, Inc., Electronic Device Deluxe Model Serial No. 8408" [or other number] Short Wave Electrodes 27300 KC 115V."

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use in the treatment of bursitis, arthritis, neuritis, neuralgia, sciatica, common forms of colds, lumbago, and chronic sinus conditions, which were the conditions for which the device was prescribed, recommended, and suggested in its advertising distributed with each device, i. e., a booklet entitled "Good Health brings Long Life and Happiness" disseminated and sponsored by and on behalf of the manufacturer and distributor of the device.

Further misbranding, Section 502 (j), the device was dangerous to health when used in the dosage, and with the frequency and duration prescribed, recommended, and suggested in its labeling, i. e., a leaflet entitled "Instruction Sheet" which was shipped with each device and which contained the following statements: "180 Watt Output 60 Cycle 115 V. A. C. Instruction Sheet Important Read The Following Instructions Carefully Before Using This Apparatus: 1. Place connecting plug into wall socket. 2. Wires of electrode pads to be inserted in Outlets marked 'Electrodes'. 3. Before starting, make certain that: a. Time switch is in zero position; 4. Place electrode pads to the area to be treated, do not cross electrode pad wires. Proper spacing is essential. For example—Place a folded turkish towel between each electrode and the body. 5. Turn time switch to the right to the desired number of minutes. This time switch automatically starts the Short Wave, as you will note by the pilot light in the center of the panel. 6. Turn heat control to the right or to the left until lowest point of meter. Then turn to the right until desired amount of heat is obtained. If too hot turn back to left until you get a comfortable heat. 7. Heat should be comfortably warm—never hot. You will find it far more beneficial to take a longer and milder treatment, than a short treatment that is uncomfortably hot. An uncomfortably hot treatment is wrong and may result in a serious burn. 8. Any metal, in the path of the Short Wave should be avoided. Bed should be non-metallic. If made of metal, cover them up with a heavy mattress. 9. Caution: Unless otherwise instructed by a physician, do not use for: Menstruation or pregnancy Gastric Ulcers Malignant Tumor Acute inflammatory Condition. 10. If any further information is desired, please telephone or write this office."

**DISPOSITION:** One device was seized, and on February 25, 1948, a default decree of condemnation was entered and the device was ordered destroyed.

#### **DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS\***

**2403. Misbranding of estrogenic substances. U. S. v. International Hormones, Inc. Plea of guilty. Fine, \$500. (F. D. C. No. 20203. Sample Nos. 30083-H, 30084-H.)**

**INFORMATION FILED:** March 17, 1947, Eastern District of New York, against International Hormones, Inc., Brooklyn, N. Y.

**ALLEGED SHIPMENT:** On or about May 5 and August 24, 1945, from the State of New York into the State of California.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the label statement "Estrogenic Substances in Sesame Oil Consisting of estrone, estradiol, estriol and other ketonic fractions derived from pregnant mares' urine" was false and

\*See also Nos. 2401, 2402.

misleading. The statement represented and suggested that the estrogenic material present in the article consisted of estrogens as they naturally occur in and are extracted from pregnant mares' urine, whereas the estrogenic material present in the article did not consist of estrogens as they naturally occur in and are extracted from pregnant mares' urine.

Further misbranding, Section 502 (b) (1), the vials of the article bore no label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), they bore no label containing a statement of the quantity of the contents; Section 502 (e) (2), they bore no label containing the common or usual name of each active ingredient of the article; and, Section 502 (f) (1), the article bore no labeling containing directions for use.

DISPOSITION: June 10, 1948. A plea of guilty having been entered, the court imposed a fine of \$500.

**2404. Misbranding of Million Dollar Tonic. U. S. v. 212 Bottles \* \* \*.**  
(F. D. C. No. 24198. Sample No. 14105-K.)

**LIBEL FILED:** January 5, 1948, Northern District of Illinois.

**ALLEGED SHIPMENT:** On or about November 25, 1947, from Richmond, Ind., by the M. L. Carpenter Medicine Co. of Dublin, Ind.

**PRODUCT:** 212 bottles of *Million Dollar Tonic* at Chicago, Ill. Examination showed that the product was an aqueous solution of extracts of plant drugs, including aloe, preserved with a small proportion of a salicylate.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the label statements "Tonic \* \* \* If taken as an intestinal tonic" were false and misleading as applied to a product which was not capable of exerting a tonic effect upon the human body or of acting as a tonic to the intestines.

Further misbranding, Section 502 (f) (2), the article was essentially a laxative and its labeling failed to bear a warning to the effect that it should not be taken by persons suffering from nausea, vomiting, abdominal pain, or other symptom of appendicitis, and that frequent or continued use of the article or use of the article in accordance with the directions on the label may result in dependence upon laxatives to move the bowels.

DISPOSITION: May 27, 1948. Default decree of condemnation and destruction.

**2405. Misbranding of Bush Mulso Tablets, Sulpho, Bush Endo-Veg, Garlic-Parsley Tablets, and Bush Lemo Tabs. U. S. v. 150 Packages, etc. Tried to the court. Judgment for the Government. Decree of condemnation and destruction.** (F. D. C. No. 19364. Sample Nos. 35078-H to 35082-H, incl.)

**LIBEL FILED:** March 18, 1946, Eastern District of Missouri.

**ALLEGED SHIPMENT:** The *Bush Mulso Tablets* were shipped by the United Health Products Co., from Burbank, Calif., on or about February 18, 1946, and the *Sulpho* was shipped by Paso Robles Lab., from Los Angeles, Calif., on or about February 19, 1946. The other products were shipped by David V. Bush, from Gardena, Calif., on or about February 25, 1946.

**PRODUCT:** 150 packages of *Bush Mulso Tablets*, 95 bottles of *Sulpho*, 143 packages of *Bush Endo-Veg*, 24 dozen packages of *Garlic-Parsley Tablets*, and 16 dozen packages of *Bush Lemo Tabs* at St. Louis, Mo. The products were being sold in St. Louis by David V. Bush during the course of a series of so-called health lectures at which he offered these products for the treatment of various disease conditions.

**LABEL, IN PART:** "Bush Mulso Tablets \* \* \* Ingredients: Each tablet contains 6 grains of charcoal and ½ grain of papain combined in an inert base of malt diastase and a vegetable gum binder"; "Sulpho \* \* \* A Concentrate of Sulphur Mineral Hot Springs Water consisting essentially of the Polysulphides and Sulphides of Calcium and Sodium"; "Bush Endo-Veg \* \* \* Ingredients—Each tablet contains Pacific Ocean Kelp as a source of iodine in a base of desiccated alfalfa and celery, with excipients"; "Garlic-Parsley Tablets \* \* \* Each Tablet contains 3 grains of dehydrated Garlic and 3 grains of dehydrated Parsley with sugar, vegetable gums and artificial color as Tablet binders and coating"; and "Bush Lemo Tabs \* \* \* Ingredients—Vitamin C in a base of powdered lemon juice and corn syrup with excipients."

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use in those diseases, symptoms, and conditions for which the articles were offered in their advertising disseminated and sponsored by and on behalf of their manufacturer, packer, and